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# Pilot, Double-Blind, Placebo-Controlled, Parallel Group Study of the Safety and Clinical Activity of CCX282-B in Patients with Moderate to Severe Crohn's Disease

**Submission date**
13/09/2005

**Registration date**
21/12/2005

**Last Edited**
11/01/2021

**Recruitment status**
No longer recruiting

**Overall study status**
Completed

**Condition category**
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**
NCT00102921

### Secondary identifying numbers
CL003_282_b

# Study information

### Scientific Title
Pilot, Double-Blind, Placebo-Controlled, Parallel Group Study of the Safety and Clinical Activity of CCX282-B in Patients with Moderate to Severe Crohn’s Disease

### Acronym
CCX

### Study objectives
The purpose of this research study is to investigate the effects of an investigational medication, called CCX282-B, on safety and on some of the symptoms of Crohn’s Disease in patients who are experiencing an active flare-up of moderate to severe Crohn’s Disease

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Not provided at time of registration

### Study design
Randomised controlled trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Not specified

### Study type(s)
Treatment

### Participant information sheet

### Health condition(s) or problem(s) studied
Crohn's Disease

### Interventions
An investigational medication, called CCX282-B (capsules), compared to placebo

### Intervention Type
Drug

### Phase

Not Specified

### Drug/device/biological/vaccine name(s)
CCX282-B

### Primary outcome measure
The primary immunologic and clinical activity objective of this study is to provide pilot information regarding the immunologic and clinical activity of daily oral doses of CCX282-B in the treatment of moderate to severe Crohn’s Disease, based on changes in the Crohn’s Disease Activity Index (CDAI).

### Secondary outcome measures
Secondary immunologic and clinical activity objectives include evaluation of the effect of CCX282-B on the Inflammatory Bowel Disease Questionnaire (IBDQ) instrument, C-reactive protein (CRP), the endoscopic appearance and biopsy of the colon and terminal ileum, and markers of leukocyte subsets and activation status.

### Overall study start date
01/08/2004

### Completion date
01/02/2006

## Eligibility

### Key inclusion criteria
1. Diagnosis of moderate to severe Crohn's Disease in small intestine; disease must be active at the time of study entry
2. Use of adequate and approved methods of birth control throughout the study period
3.
Willing and able to sign an informed consent

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
70

### Key exclusion criteria
1. Pregnant or breastfeeding
2. Infection with hepatitis B, hepatitis C, or human immunodeficiency virus (HIV; the virus that causes AIDS)
3. Abuse of alcohol or of illegal drugs

**Date of first enrolment**
01/08/2004

**Date of final enrolment**
01/02/2006

# Locations

**Countries of recruitment**
Netherlands

**Study participating centre**
**Meibergdreef 9**
Amsterdam
Netherlands
1105 AZ

# Sponsor information

**Organisation**
ChemoCentryx (USA)

**Sponsor details**
850 Maude Avenue
Mountain View
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**Sponsor type**
Industry

**Website**
http://www.chemocentryx.com/

**ROR**
https://ror.org/04gp12571

# Funder(s)

**Funder type**
Industry

**Funder Name**
ChemoCentryx

# Results and Publications

**Publication and dissemination plan**
Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration